

REMARKS/ARGUMENTS

A. Status of the Claims

Claims 1, 7 and 8 have been amended without prejudice. Support for the amendments can be found, e.g., in original claims 1, 7 and 8, and on page 1, first paragraph after section heading OBJECT OF THE INVENTION and on page 8, in the paragraph immediately above section heading SPECIAL ACTIONS OF THE INVENTION, all of the original specification as filed.

Claim 9 has been amended to incorporate the features of claim 1.

New claims 13 and 14 have been added. Support for these claims can be found, e.g., in the original claim 1.

Claims 1-14 are now pending, with claims 9-12 withdrawn from the consideration until their rejoinder.

Applicants respectfully submit that no new matter has been added by virtue of this amendment.

B. Written Description (New Matter) Rejection

In the Office Action, claims 1-6 were rejected under 35 U.S.C. § 112, first paragraph, “as failing to comply with the written description requirement” for the term “more than 2%” in claim 1.

In response, Applicants submit that the proportion of melatonin in claim 1 has been amended without prejudice back to the way it was recited in original claim 1 – “melatonin in a proportion of from 0.1% ~~from more than 2%~~ to 5% of the oral hygiene product by weight.” Applicants note that the amendment does not introduce new matter, as the amendment is

supported, e.g., by original claim 1, and the original specification as filed, e.g., on page 8, last paragraph, and page 9, first paragraph.

Accordingly, Applicants respectfully request withdrawal of the rejection.

C. Anticipation Rejections

1. U.S. Patent No. 6,998,112 to Zuckerman

Claims 1, 3, 4, and 8 were rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,998,112 to Zuckerman (“the Zuckerman patent”).

In response, Applicants submit that the Zuckerman patent is not properly citable as prior art under 35 U.S.C. § 102(e) against the present application, as it was filed after the priority date of the present application.

The present application was filed on November 25, 2003, claiming priority to Spanish patent application 200202810, filed December 9, 2002.

The Zuckerman patent was filed on March 18, 2003. Accordingly, Applicants submit that the 35 U.S.C. § 102(e) of the Zuckerman patent is March 18, 2003. See, e.g., 35 U.S.C. § 102(e).

Because the 35 U.S.C. § 102(e) date of the Zuckerman patent (March 18, 2003) is after the priority date of the present application (December 9, 2002), the application for the Zuckerman patent was not “filed in the United States before the invention by the applicant for patent” as recited in 35 U.S.C. § 102(e). See, 35 U.S.C. § 102(e). Therefore, the Zuckerman patent is not properly citable as prior art under 35 U.S.C. § 102(e) against the present application. See, *Id.*

Applicants note that (i) the certified copy of the priority document (Spanish patent application 200202810) has been filed on February 20, 2004; and (ii) as indicated on page 2 of the Office Action mailed on July 16, 2007, has been received by the USPTO.

Applicants further note an English translation of the specification of the priority document, along with a statement that the translation of the certified copy is accurate, is attached to this response as Appendix A.

Applicants respectfully remind the Examiner that MPEP states that:

A rejection based on 35 U.S.C. 102(e) can be overcome by:

....

(E) Perfecting a claim to priority under 35 U.S.C. 119(a)-(d) within the time period set in 37 CFR 1.55(a)(1) or filing a grantable petition under 37 CFR 1.55(c). See MPEP § 201.13. The foreign priority filing date must antedate the reference and be perfected. The filing date of the priority document is not perfected unless applicant has filed a certified priority document in the application (and an English language translation, if the document is not in English) (see 37 CFR 1.55(a)(3)) and the examiner has established that the priority document satisfies the enablement and description requirements of 35 U.S.C. 112, first paragraph...

See MPEP, Section 706.02(b).

Applicants respectfully request that the Examiner acknowledge that the priority claim to Spanish patent application 200202810, filed December 9, 2002, has been perfected, and request withdrawal of the anticipation rejection over the Zuckerman patent.

For the sake of completeness, Applicants submit that the Zuckerman patent does not teach an oral hygiene product with anti-oxidant and immuno-stimulating activity as recited in the present claims, and, instead, is directed to a sleep inducing toothpaste. See, e.g., Abstract.

2. U.S. Patent No. 6,200,550 to Masterson

Claims 1, 2, 3, 4, 6, and 8 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 6,200,550 to Masterson (“the Masterson patent”).

In response, Applicants submit that claim 1 has been amended without prejudice to recite in part “[a]n oral hygiene product with anti-oxidant and immuno-stimulating activity ...”.

Applicants submit that the Masterson patent is directed to an oral care composition comprising Coenzyme Q₁₀. See, e.g., Abstract. The Masterson patent states that Coenzyme Q₁₀ is an antioxidant. See, e.g., column 1, lines 5-10. However, Applicants submit that the Masterson patent fails to mention anything about “immuno-stimulating activity” of any compounds, and therefore, does not teach “[a]n oral hygiene product with anti-oxidant and immuno-stimulating activity ...” as recited in amended claim 1.

With regard to new claim 13, Applicants submit that the Masterson patent does not teach or suggest an oral hygiene product with the “active consisting essentially of melatonin” as recited in claim 13, because the active of the Masterson patent will necessarily include Coenzyme Q₁₀. See, e.g., Abstract.

With regard to the Examiner statement that “the examiner does not agree [with the Applicants’ argument that the Masterson patent does not disclose a specific percentage of melatonin since the range of 0.1 to 20 percent given at the first paragraph of column 7¹ relates to tocopherol and B-carotene only] ... since it is a literal reading based purely on the word-for-word construction of the sentence ...”, Applicants respectfully remind the Examiner that MPEP states:

¹ the passage recites: “ Suitable antioxidants include, but are not limited to, tocopheryl acetate, β-carotene, ascorbic acid, and melatonin. Tocopheryl acetate and β-carotene are most preferred for use in the present invention and are used at a concentration of between about 0.1% to about 20%, preferably they are used between about 0.2% and about 2% by weight.”

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "**The identical invention must be shown in as complete detail as is contained in the ... claim.**" *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

See, MPEP, Section 2131. (emphasis added).

Applicants further submit that the Masterson patent cannot anticipate claim 1, because the range of "0.1% to 5%" for melatonin as recited in claim 1 is not found in the Masterson patent. See, MPEP, Section 2131. Applicants note that the range relied upon by the Examiner in making the rejection is for tocopheryl acetate or β -carotene only, and not for melatonin.

Accordingly, Applicants request withdrawal of the rejection.

Applicants note that melatonin and Coenzyme Q₁₀ are completely different in their chemical structure and potency. Applicants submit that melatonin is a direct antioxidant, and that it reinforces the concentrations and action of human antioxidant enzymes, such as glutathione reductase and reduced glutathione, and it has anti-inflammatory actions, as it blocks the action of inflammatory interleukins and prostagladins. Accordingly, Applicants submit that melatonin is different than Coenzyme Q₁₀. See, e.g., Cuanto A., et al., "Relationship between salivary melatonin levels and periodontal status in diabetic patients, J. Pineal Res. 2003; 35:239-244; See also, Cutando A, et al., "Local application of melatonin into alveolar sockets of beagle dogs reduces tooth removal-induced oxidative stress", J. Periodontol 2007; 78:576-83 (copies of both articles are attached as Appendix B). Applicants note that an overlap in a mechanism of action of this compounds (i.e., both being antioxidants) should not preclude patentability of the present claims.

For the foregoing reasons, Applicants respectfully request withdrawal of the rejection.

D. Obviousness Rejection

In the Office Action, claims 1-8 were rejected under 35 U.S.C. § 103 (a) over U.S. Patent No. 6,509,007 to Rajaiah et al. (“the Rajaiah patent”) in view of the Masterson patent.

In responding to the Applicants’ argument that the references are not properly combinable, the Examiner stated:

Rajaiah et al teach that their coatings “provide[s] sufficient substantivity to provide sustained release of an oral care active ... Thus, if anything, one would presume this would actually improve the availability of Coenzyme Q₁₀, given that it is **hydrophobic like polybutene**.

See Office Action, page 6 (emphasis added).

In response, Applicants respectfully direct the Examiner’s attention to column 4, lines 11-21 of the Masterson patent, where it is stated:

The compositions of the present invention comprise Coenzyme Q₁₀ combined with a solubilizing agent. As used in the present invention a solubilizing agent must be capable of fully solubilizing Coenzyme Q₁₀ in a **water based** oral care composition. Also, the solubilizing agent must be pharmaceutically acceptable, i.e., non-toxic to cells or tissues. The solubilizing agent of the present invention must also be capable of preventing Coenzyme Q₁₀ from precipitating from an oral care composition, and from forming a heterogeneous, unstable, composition which has unfavorable tactile and taste characteristics.

See the Masterson patent, column 4, lines 11-21.

Applicants respectfully submit, based on this passage, that Coenzyme Q₁₀ when formulated into the oral care compositions of the Masterson patent is solubilized in the **water based composition**, and therefore, contrary to the Examiner’s assertion, is not “hydrophobic like polybutene.”

Applicants further note that the Masterson patent specifically states that solubilizing Coenzyme Q₁₀ in lipids (hydrophobic materials) “provides a commercial

product **having unfavorable consumer reaction.**" See, column 2, lines 21-23 (emphasis added).

Accordingly, Applicants submit that one skilled in the art would not have been prompted by the combined teachings of the cited reference to combine Coenzyme Q₁₀ solubilized in the **water based composition** (as described in the Masterson patent) with **hydrophobic like polybutene** (as described in the Rajaiah patent) and expect improve the availability of Coenzyme Q₁₀, at the very least because the Masterson patent explicitly states solubilizing Coenzyme Q₁₀ in lipids (hydrophobic materials) "provides a commercial product having **unfavorable consumer reaction.**" See, column 2, lines 21-23.

Applicants further submit that, in the event references were properly combinable (a position which is refuted), the combination of the cited references would not have rendered the present claims obvious.

The Examiner acknowledged in the Office Action of January 4, 2007, that the Rajaiah patent "does not specifically disclose the relative proportion of the antioxidants...". The Examiner, then, relied on the Masterson patent to cure this deficiency.

Applicants respectfully submit that, for the reasons discussed above, the Masterson patent cannot cure this deficiency in the Rajaiah et al., as the Masterson patent does not teach or suggest an oral hygiene product comprising "...melatonin in a proportion of from 0.1% to 5% of the oral hygiene product by weight," as recited in independent claims 1, 7 and 8.

Applicants further submit that the Rajaiah patent states with regard to the actives of the compositions described therein:

The oral care actives incorporated within the composition, and optionally included within the oral care kits, can be selected from the group consisting of anti-calculus or anti-tartar agents, fluoride ion sources, stannous ion sources,

whitening agents, anti-microbial and anti-plaque agents, anti-inflammatory agents, nutrients, antioxidants, anti-viral agents, anti-fungal agents, analgesic and anesthetic agents, H-2 antagonists, fragrances and sensates, components other than polybutene which impart a clean feel to the teeth, pigments and colorants, and mixtures thereof.

See, column 2, lines 14-23.

Applicants note that the Rajaiah patent does not list an active with “immuno-stimulating activity”. Accordingly, Applicants submit that the Rajaiah patent does not teach or suggest “[a]n oral hygiene product with anti-oxidant and immuno-stimulating activity” as recited in the present claims.

As discussed above, the Masterson patent also does not teach or suggest “[a]n oral hygiene product with anti-oxidant and immuno-stimulating activity” as recited in the present claims. Accordingly, Applicants submit that the Masterson patent again does not cure the deficiency of the Rajaiah patent.

Therefore, Applicants submit that the combination of the cited references does not render the present claims obvious for this additional reason, as the combination does not teach or suggest each and every element of the present claims.

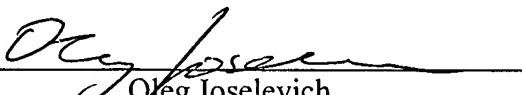
With regard to new claim 13, Applicants submit that the combination of the cited references does not teach or suggest an oral hygiene product with the “active consisting essentially of melatonin” as recited in claim 13.

Accordingly, Applicants submit that the combination respectfully request withdrawal of the obviousness rejection.

CONCLUSION

An early and favorable action of the merits is earnestly solicited.

Respectfully submitted,
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APPENDIX A